

Initial REMS Approval: August 4, 2015

**ANDA 204268 Testosterone Topical Gel, 1.62%, CIII**

**Drug Class and Formulation: Testosterone Gel Products**

Perrigo Israel Pharmaceuticals Ltd.

Industrial Zone

Yeruham, Israel 80500

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL(s):**

To inform patients about the serious risks associated with the use of testosterone gel.

**II. REMS ELEMENTS:**

**A. Medication Guide**

A Medication Guide will be dispensed with each Testosterone Topical Gel, 1.62%, prescription in accordance with 21 CFR § 208.24.

The Medication Guide is appended.